

RESPONSE

Claims 1, 3, 4, 6, 7 and 10-12 have been rejected as being anticipated by the Doran '799 patent. Claims 2, 5, 8 and 9 have been rejected as being obvious in view of the Doran '799 patent. In view of the foregoing amendments, and for one or more of the following reasons, Applicants submit that the rejection is traversed.

The Examiner "bears the initial burden, on review of the prior art . . . , of presenting a *prima facie* case of unpatentability." In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

An obviousness rejection cannot be predicated on the mere identification of individual components of claimed limitations. There must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998). "[I]t is incumbent upon the examiner to identify some suggestion to combine the references or make the modification." In re Mayne, 104 F.3d 1339, 1342 (Fed. Cir. 1997). The showing of obviousness must be clear and particular, and broad conclusory statements about the teaching of one or more references, standing alone, are not evidence. Brown & Williamson Tobacco Corp. v. Phillip Morris, Inc., 229 F.3d 1120, 1125 (Fed. Cir. 2000). Finally, it is improper to use an inventor's patent as an instruction book on how to reconstruct the prior art. Panduit Corp. v. Dennison Manufacturing Co., 810 F.2d 1561 (Fed. Cir. 1987).

Before discussing the specific references, it is necessary first to understand the anatomical mechanism associated with the terms supination and pronation. Supination and pronation of a forearm are described in the medical literature as being a function of

the elbow. The musculature that creates supination/pronation originates at the elbow, and rotation occurs along the radius and ulnar bones of the forearm. Attached are copies of excerpts from two medical references describing the functions of the elbow as including the supination and pronation of the forearm.

Turning now first to the Doran '799 reference, Applicants respectfully submit that the Examiner has not accurately described that reference. Doran has an arm cuff 20 (and related straps 25 and 27) and wrist cuff 50. These two separate and independent cuffs are attached to each other by a wrist connector 30. The wrist connector 30 attaches a forearm platform 26 by a swing arm 30 to the wrist cuff 50. Anatomically, the orthosis of Doran creates a pivot axis in the wrist of the patient. Doran does not serve the function of rotating the forearm from the elbow down to the hand of the patient. Accordingly, Applicants submit that even though the Doran reference uses the terms "supination" and "pronation", it is not using those terms in the same way as the medical literature describes it, nor in the same way as intended by Applicants. In fact, the title of Doran "Orthosis For Supination And Pronation Of The Wrist" is, on its face, inconsistent with the basic and fundamental definition that supination and pronation is a function of the elbow.

The present invention is directed to supination and pronation as it is recognized in the medical field with respect to an elbow function. The claimed invention includes the rotation of the total forearm enclosure. It is for this reason that the claimed invention includes a forearm enclosure adapted to substantially wrap around a forearm. Further, the claims have been amended to emphasize the elbow function by including the upper arm support member which is required to obtain the proper supination/pronation function of the elbow. Accordingly, Applicants' invention is medically and anatomically

distinguished from the Doran wrist orthosis as a result of this fundamental difference in the recognition and operation of the elbow function with supination and pronation.

In addition to the foregoing, Applicants note at least several specific aspects of Doran that Applicants believe were incorrectly identified by the Examiner. First, Doran does not include any forearm enclosure and forearm support member adapted to slidably receive a forearm enclosure. Instead, as noted earlier, Doran merely includes an arm cuff 50 and a wrist cuff 20 that are separate from each other (although connected by swing arm 33). Second, there is no rotational force of supination/pronation in Doran. As explained earlier, in Doran, the patient's wrist is the pivot axis, so there is no rotational force of supination and pronation as claimed. Third, the flexible tension member (71A or 71B) described in Doran creates a pivot around the wrist axis, not in the rotation of supination and pronation of a forearm. This is evident in Figure 3 and the description of that figure in column 3, lines 44-55.

Applicants further respectfully disagree with the Examiner's rejection of claims 8 and 9 on the basis of obviousness. The alternative constructions of the upper arm support member are not equivalent to the structures seen in Doran as urged by the Examiner. The specific and significant importance of these variations is discussed on pages 6 and 11 of the present application with respect to the angle of connection of the upper arm support to the forearm support. As can be seen, this angle of connection is potentially clinically significant for the reasons given. It is unfair to call those constructions equivalent constructions without any basis for that statement.

Finally, the Office Action cites the Hamersly '353 patent, but it does not cite the reference with respect to any rejection. Hamersly is, in gross terms, representative of a

pivotal elbow brace in the state of the art. It is not relevant, nor does it disclose or teach the elbow functions of supination and pronation. Applicants reserve the right to distinguish this reference further if it is ever specifically identified as a basis for a rejection.

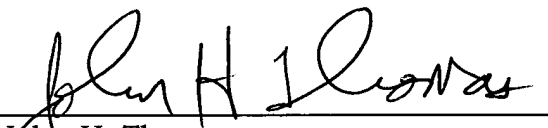
For one or more of the forgoing reasons, Applicants submit that the application is now in condition for allowance, favorable action is requested hereon.

The Commissioner is hereby authorized to charge any deficiencies in payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-2127.

Respectfully Submitted,

April 12, 2004

Date



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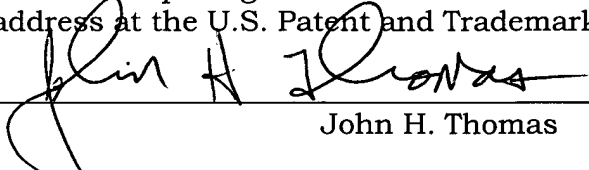
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Date: April 12, 2004